

NOV 2005

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 52-R-0006
CUSTOMER NUMBER: 507

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Covance Laboratories Inc.
9200 Leesburg Turnpike
Department Of Laboratory Animal Medicine
Vienna, VA 22182

Telephone: (b)(2)High, (b)(7)f

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	100	919	338	0	1,257
5. Cats	0	0	0	0	0
6. Guinea Pigs	21	0	176	0	176
7. Hamsters	0	22	0	0	22
8. Rabbits	309	354	2,493	0	2,847
9. Non-human Primates	131	1,201	495	27	1,723
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

(B)(6) (B)(7)(c)

DATE SIGNED

29 Nov 05

Covance Laboratories, Inc., Vienna, VA Column E explanations.
Facility Registration #52-R-0006.

A total of 27 primates were reported with research use designated as USDA category E. Additional information related to each study is provided below.

A study was conducted to investigate b4 of a test compound in cynomolgus monkeys as a part of a FDA required New Drug Application (NDA). The test-compound was a b4 b4

Three animals developed areas of mild to moderate (b)(4) One animal, having moderate presentation of the condition, was euthanized the day after presentation. Two animals, having mild presentation of the condition, were monitored without medical intervention. The test-compound was a systemic b4 which could have been used for treatment of the condition. The scientists conducting this study had significant concerns regarding antagonistic effects of additional b4 The animals' conditions did not deteriorate after initial presentation through the end of the study.

The purpose of the study was to investigate b4 in cynomolgus monkeys as a part of a FDA required New Drug Application (NDA). The test-compound was a b4 One b4 animal developed b4 Treatment with b4 per oral gavage was started the day of the initial presentation. The next day the treatment was discontinued due to concern about interaction with test compound, and the animal was euthanatized. One animal was not treated with an antibiotics after extraction of an infected tooth. Use of antibiotics after tooth extractions was considered by the veterinarian to be discretionary treatment. The animal was examined daily by highly qualified technicians, and recovered uneventfully. Test-article was a b4 capable of affecting numerous biochemical pathways and organ systems, including liver, kidney, heart, GI tract, and bone marrow. The potential for broad systemic effects created a significant scientific concern over the confounding effects of drugs used for treatment of animals.

A study was conducted to investigate b4 activity of the test-compound in cynomolgus monkeys as a part of a FDA required New Drug Application (NDA). The test compound was an b4 with activity against b4 One animal developed b4 . A four-day treatment with SQ fluids was started the following day. Treatment with b4 was briefly delayed while the scientific impact of drug interaction was considered. The animal was examined daily by highly qualified technicians and no deterioration of animal's condition was noted. The additional treatment was initiated, and after four days, stool became normal.

The purpose of the study was to investigate test compound b4 in cynomolgus monkeys as a part of a FDA required New Drug Application (NDA). The test-compound was a b4 One animal developed right rear non-weight bearing lameness with swelling of the right knee. A distal physeal femoral fracture was diagnosed. The animal was euthanized three days after the definitive diagnosis was made. No analgesics were provided. The animal maintained normal attitude and appetite and did not appear in obvious pain/distress.

A study was started in September of 2004 and ended in November 2004. Total of 20 rhesus monkeys were placed in category E. The following was reported in 2004 reporting period:
Animals were used on FDA-mandated b4 aimed to develop and characterize the best b4 medication. Based on FDA requirements only partial palliative/symptomatic treatment could be provided to animals. Animals were observed more frequently and those in pain/distress were euthanized.